HEALTH AND SENIOR SERVICES
DIVISION OF HEALTH CARE SYSTEMS ANALYSIS

Hospital Licensing Standards

Proposed Amendments: **N.J.A.C. 8:43G-1.2, 8.1, 8.2, 8.4, 8.6, 8.7, 13.1, 13.4, 13.5, 13.8, 13.9, 13.10, 13.11, 13.13, 13.15, 14.1, 14.3, 14.5, 14.7, 14.8, 20.2 and 24.8**

Proposed New Rules: **N.J.A.C. 8:43G-8.3, 8.8, 13.16, through 13.22 and 24.9**

Proposed Repeals: **N.J.A.C. 8:43G-8.9, 8.12, 8.13, 14.6 and 14.9 through 14.16**

Authorized By: _____
Clifton R. Lacy, M.D., Commissioner, Department of Health and Senior Services (with the approval of the Health Care Administration Board).

Authority: N.J.S.A. 26:2H-1 et seq.

Calendar Reference: Please see Summary below for statement of exception to the rulemaking calendar requirements.

Proposal Number: PRN 2003-200

Submit written comments by September 5, 2003 to:

John A. Calabria, Director
Certificate of Need and Acute
Care Licensure Program
P.O. Box 360, Room 403
Trenton, New Jersey 08625-0360

The agency proposal follows:

Summary

The Department of Health and Senior Services (the Department) is proposing amendments, new rules and repeals to those subchapters dealing with infection control practices in both the Hospital Licensing Standards, N.J.A.C. 8:43G, and the Licensing Standards for Ambulatory Care Facilities, N.J.A.C. 8:43A. This proposal amends the infection control practices in the hospital licensing standards (N.J.A.C. 8:43G) and a companion proposal published elsewhere in this issue of the New Jersey Register amends the infection control practices for licensed ambulatory care facilities (N.J.A.C. 8:43A).

The amendments, new rules and repeals which follow are intended to improve the effectiveness of infection control practices in licensed New Jersey health care facilities. The proposed amendments, new rules and repeals are the work of a committee, composed both of representatives from the Department and of infection control professionals from New Jersey's health care industry, which was convened to review and revise licensing standards for infection control in both hospitals and ambulatory care facilities. The primary aim of this effort was to update the standards, which have not been substantially revised since 1990, to reflect current infection control theory and practice, and thereby reduce the extent of nosocomial infections in New Jersey's health care facilities. However, the proposed amendments, new rules and repeals are also an attempt to carry out the State Legislature's stated intent in P.L. 1998, c.43 to rely less on the certificate of need process and more on licensure and inspections of health care facilities to ensure the provision of high quality health care to New Jersey citizens. In pursuing these dual goals of making the existing standards current and ensuring quality care through the licensure and inspection process, the committee tried to make the existing standards more specific rather than impose a large number of entirely new requirements.

What follows are proposed amendments, new rules and repeals to N.J.A.C. 8:43G-14, the Infection Control subchapter of the Licensing Standards for Hospitals. In addition, amendments have been made to the following subchapters, which deal with subjects related to infection control:

N.J.A.C. 8:43G-8, Central Supply
N.J.A.C. 8:43G-13, Housekeeping and Laundry
N.J.A.C. 8:43G-24, Plant Maintenance and Fire and Emergency Preparedness

In certain areas entire sections of a subchapter have been recodified to another subchapter. It was the consensus of the committee that the infection control elements of the licensing standards would be better organized if N.J.A.C. 8:43G-14 outlined the core elements of current theory and practice, and that the specific infection control aspects of Central Supply, Housekeeping, and Laundry were better placed in each of those individual subchapters. This is the general organizational technique followed in these amendments and recodifications.

The Committee also proposed another recodification which, if adopted, will be found not in the chapters listed above but in the respective section on "Employee Health" (N.J.A.C. 8:43G-20.2): This is a requirement that not only employees of a facility, but any member of the medical staff with privileges to practice in a licensed facility be required to have a Mantoux tuberculin skin test. The protocols for Mantoux testing have also been amended by the Department's Tuberculosis Control Program to reflect current guidelines from the Centers for Disease Control (CDC). These guidelines are discussed in detail in this Summary below at the discussion of N.J.A.C. 8:43G-20.2.

In N.J.A.C. 8:43G-24, a new rule, N.J.A.C. 8:43G-24.9, has been added to the subchapter on Physical Plant which requires that when construction or renovation is contemplated in a health care facility, an assessment be made of the project's potential impact on nosocomial infections, and that if necessary preventive measures be undertaken before the construction is initiated.

The amendments, new rules and repeals to infection control standards are summarized below:

N.J.A.C. 8:43G Licensing Standards for Hospitals.

Subchapter 1 General Provisions

N.J.A.C. 8:43G-1.2, Definitions, includes a definition of "all payers case mix index (CMI)," which is a measure of the complexity and intensity of a hospital's cases, and the extent of resources required to treat them. The CMI is used in the calculation of adjusted occupied beds at N.J.A.C. 8:43G-14.5(b) using the most recent complete data set available to the Department, which in turn determines the amount of required infection control professional staffing.

Subchapter 8. Central Supply

To broaden its scope, the heading of this subchapter has been changed from "Central Supply" to "Central Service."

N.J.A.C. 8:43G-8.1(e) is amended to add the requirement that methods for processing reusable medical devices conform to the latest publications from the Association for Advancement of Medical Instrumentation (AAMI), and lists the current editions. This is an example of the proposed revisions making the existing standards more specific.

The AAMI publications can be summarized as follows:

1. "Good Hospital Practice: Steam Sterilization and Sterility Assurance," ST 46: This recommended practice provides guidelines for steam sterilization in hospitals and similar health care facilities. These practice standards sets forth guidelines for facility design and work practices to assist health care personnel in developing procedures to achieve and maintain the sterility assurance level of devices sterilized by saturated steam under pressure. (N.J.A.C. 8:43G-8.1(e)1)

2. "Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use," ST 37: The guidelines contained in this document are intended to assist health care personnel in: assuring the sterility of devices and materials processed by flash steam sterilization; maintaining the sterility of processed items until the point of use; and promoting good infection control and safe handling practices. Flash sterilization can be

performed in various areas of the health care facility, including the operating room, labor/ delivery room, and emergency/trauma room. (N.J.A.C. 8:43G-8.1(e)2)

3. "Safe Use and Handling of Gultaraldehyde-based Products in Health Care Facilities," ST 58: This recommended practice provides guidelines for the safe use and handling of Gultaraldehyde as a disinfectant and sterilant in health care facilities by defining facility design considerations, work practices, and engineering controls including ventilation recommendations, that will help reduce personnel and patient exposure to Glutaraldehyde. (N.J.A.C. 8:43G-8.1(e)3)

4. "Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities," ST 33: These guidelines are intended to increase assurance of sterility by identifying the special considerations that apply to this packaging method and by providing recommendations on the proper use of the container system. These recommendations address cleaning, decontamination, preparation, assembly, loading, quality assurance, sterile storage, transport and process performance. (N.J.A.C. 8:43G-8.1(e)4)

5. "Steam Sterilization and Sterility Assurance Using Table Top Sterilizers in Office-based, Ambulatory Care, Medical, Surgical and Dental Facilities," ST 42R: This recommended practice specifically addresses; functional and physical design criteria for work areas; staffing, education and other personnel considerations; sterilization processing procedures; installation, care and maintenance of table top steam sterilizers; quality control and continuous quality improvement. (N.J.A.C. 8:43G-8.1(e)5)

6. "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes:" The reprocessing protocol presented in this recommended practice outlines basis steps to clean and process gastrointestinal endoscopes. It covers preparing the endoscopes for cleaning, leak testing, cleaning, rinsing, high level disinfection, drying and storage. (N.J.A.C. 8:43G-8.1(e)6)

7. "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Non-clinical Setting," ST 35: The biological decontamination process includes through cleaning, and whenever necessary for personnel or patient safety, appropriate application of a microbioiolal process (disinfection or sterilization) This recommended practice addresses; design criteria for decontamination areas; staffing, education and other personnel considerations; immediate handling of contaminated items at the point of use; transport of contaminated items, and decontamination processed. (N.J.A.C. 8:43G-8.1(e)7)

8. "Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness," ST 41R: This recommended practice specifically addresses; design considerations for EO sterilization processing areas; staff qualifications, education, and other personnel considerations; processing procedures; installation, care, and maintenance of EO sterilizers; and quality control. (N.J.A.C. 8:43G-8.1(e)8)

N.J.A.C. 8:43G-8.2 and 8.3 are amended to add experience, certification, and training requirements for personnel in Central Service.

N.J.A.C. 8:43G-8.4(a)1 is amended to require hospital laundered scrubs for personnel in central service in order to protect both the worker and the patients.

Concerning N.J.A.C. 8:43G-8.4(d), the Department's surveyors often find sterile supplies with an expired shelf life. This section attempts to focus upon the fact that storage techniques can have a direct bearing on sterility and infection control. The proposed amended language requires adherence to manufacturer recommended shelf life dates for sterile supplies, a 30-day maximum shelf life for muslin blends, and the establishment and enforcement of policies and procedures to retrieve and reprocess outdated supplies.

The existing requirements for sterile supply handling is deleted (N.J.A.C. 8:43G-8.4(e)) and replaced with more specific requirements that include criteria regarding "event related sterility programs." The existing criteria regarding single use items is deleted (N.J.A.C. 8:43G-8.4(f)) and replaced with a new section (N.J.A.C. 8:43G-8.5(a) through (c)). N.J.A.C. 8:43G-8.5(a) delineates strict conditions under which single use patient care items may be reprocessed, either in-house or by an outside party, the methods for doing so, and documentation to be maintained. Food and Drug Administration (FDA) reprocessing rules are cited by reference at N.J.A.C. 8:43G-8.5(a)2i and ii. These FDA rules, which are incorporated therein by reference, as amended and supplemented, can be briefly summarized as follows:

1. "Pre-market notification, registration and listing, Title 21 Code of Federal Regulations," Part 807: Generally, owners and operators of establishments who process single use devices must register their establishment with the Food and Drug Administration (FDA) and list each device.

2. "Quality Systems Regulations," 21 CFR Part 807: Current good manufacturing practice (CGMP) requirements are set forth in the quality system regulation that governs the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices.

New language at N.J.A.C. 8:43G-8.5(b) cites OSHA requirements for the transport of contaminated equipment. These rules are also incorporated therein by reference, as amended and supplemented. Briefly summarized, OSHA's Blood Borne Pathogens Regulation, (29 CFR 1910.1030), requires employers to establish written control plans to eliminate or minimize employee exposures to pathogenic microorganisms that are present in human blood and can cause disease in humans. This standard addresses handling, transport, labeling, and decontamination of reusable medical instruments contaminated with blood or body fluids (N.J.A.C. 8:43G-8.5(b)). Lastly, new language at N.J.A.C. 8:43G-8.5(c) establishes standards for multi-hospital shared reprocessing. These requirements include unified policies and procedures approved by all participating

facilities in the network in conjunction with infection control managers (8:43G-8.5(c)1); inventorying and pre-cleaning of instruments prior to transport (N.J.A.C. 8:43G-8.5(c)2); decontamination, assembly and sterilization performed in accordance with manufacturer's written recommendations (N.J.A.C. 8:43G-8.5(c)3); processing facility records maintained (for example, sterilization logs, biological monitoring documentation consistent with 8.8(a)) (N.J.A.C. 8:43G-8.5(c)4); and, the transport of sterile product using disinfected, impervious, sealed or locked containers (N.J.A.C. 8:43G-8.5(c)5).

In N.J.A.C. 8:43G-8.7, the existing standards have been made more specific. "Scrupulous cleaning" and categorization (that is, critical, semicritical, noncritical) of devices is being required prior to sterilization or disinfection (N.J.A.C. 8:43G-8.7(a)). Invasive devices are to be sterilized or disinfected in accordance with manufacturer's "written" recommendations or according to infection control committee policy (N.J.A.C. 8:43G-8.7(b)). The criteria for examining and repairing reusable linens is set forth at N.J.A.C. 8:43G-8.7(c). Just in time or immediate use only cleaning techniques ("flash sterilization") are described in N.J.A.C. 8:43G-8.7(d).

N.J.A.C. 8:43G-8.8 is a section which revises the existing sterilization monitoring criteria being deleted from N.J.A.C. 8:43G-8.13 and makes it more specific and detailed. N.J.A.C. 8:43G-8.8(a) outlines the biological monitoring schedule for each type of sterilization agent (that is, ethylene oxide, peracetic acid, low temperature gas plasma, steam). N.J.A.C. 8:43G-8.8(b) requires that the biological indicator to be used is applicable to the sterilization process and stored consistent with manufacturer's recommendations. N.J.A.C. 8:43G-8.8(c) requires a biological monitor with live spores to be performed following repair or breakdown of the sterilization equipment. N.J.A.C. 8:43G-8.8(d) requires the sterilization process for implantables to use a biological monitor and to await the results prior to the use of the implantables. N.J.A.C. 8:43G-8.8(e) requires a chemical indicator to be used that is applicable to the sterilization process to be used (that is, steam, ethylene oxide, gas plasma, peracetic acid). N.J.A.C. 8:43G-8.8(f) requires effective corrective action, including retesting and recalls if necessary, and documentation in the event of a positive biological test of a sterilizer. In the event of a positive biological result of single use medical devices that are outsourced to shared reprocessing centers, N.J.A.C. 8:43G-8.8(g) requires immediate notification by the processing facility made to the receiving facility.

N.J.A.C. 8:43G-8.9 has been deleted and the requirements for staff education recodified to N.J.A.C. 8:43G-8.3.

N.J.A.C. 8:43G-8.11(b) is amended to indicate more clearly that defective instruments and equipment are not to be used. N.J.A.C. 8:43G-8.11(f) is deleted (that is, recodified as part of N.J.A.C. 8:43G-8.1(e)) and replaced with language requiring a record to be kept of each sterilization/disinfection load for at least one year. N.J.A.C. 8:43G-8.11(h) is added requiring an indicating thermometer for all ethylene oxide aeration equipment and N.J.A.C. 8:43G-8.11(i) requires all sterilizers to be maintained in accordance with the manufacturer's instructions.

N.J.A.C. 8:43G-8.12 and 8.13, have now been recodified and relocated to other sections of Subchapter 8, and in some cases made more specific. N.J.A.C. 8:43G-8.12 has been recodified in its entirety to N.J.A.C. 8:43G-8.6(a). All of the criteria previously contained at N.J.A.C. 8:43G-8.13(a) through (g) have been recodified as follows: 8:13(a) to 8.11(i); 8.13(b) to 8.11(h); 8.13(c) to 8.11(f); 8.13(d) to 8.4(d); 8.13(e) to 8.11(f); 8.13(e)1-4 to 8.8(a)-(d); 8.13(f) to 8.8(f) and 8.13(g) to 8.8(e)2. These amendments detail procedures to be followed to ensure that a sterile environment is maintained at all times.

Subchapter 13. Housekeeping, Laundry, and Sanitation

The main change to this subchapter is that all of Subchapter 14, Infection Control, relating to sanitation and solid waste disposal, beginning with N.J.A.C. 8:43G-14.9 through the end of the subchapter, has been recodified to Subchapter 13, which was formerly just Housekeeping and Laundry.

N.J.A.C. 8:43G-13.1(a) is amended to provide that housekeeping policies and procedures are to be reviewed every three years or as needed rather than annually.

N.J.A.C. 8:43G-13.1(c) and (d) are amended to require that materials safety data sheet is more specific than “a list of the antidotes” currently required be kept for cleaning and disinfecting agents, pesticides and herbicides. N.J.A.C. 8:43G-13.1(e) adds clarification that the product name and use of cleaning and disinfecting agent labeling must be as specified by the manufacturer. N.J.A.C. 8:43G-13.1(f) states that pesticides are to be applied in accordance with the State Pesticide Control Code which may be found at N.J.A.C. 7:30.

N.J.A.C. 8:43G-13.4(m) is amended to require that housekeeping and cleaning supplies to be used must be approved by the Infection Control Committee.

N.J.A.C. 8:43G-13.4(q), (r), & (s) are three new housekeeping standards intended to improve cleanliness in storage areas and reduce the possibility of the spread of infection through communal toys and potted plants.

At N.J.A.C. 8:43G-13.8 “quality assurance” has been changed to “quality improvement.” The same change is made elsewhere in this subchapter.

N.J.A.C. 8:43G-13.9 is amended to require laundry policies and procedures to be reviewed every three years or more frequently as needed (rather than the previous annual requirement) and to require the approval of the infection control committee (N.J.A.C. 8:43G-13.9(a)). This is consistent with similar amendments to central service policies and procedures (N.J.A.C. 8:43G-8.1(a)). N.J.A.C. 8:43G-13.9(b) is amended to state that all used laundry is to be considered contaminated and handled in accordance with the policies and procedures (rather than protocols) that are approved by the infection control committee. The need for the approval of these policies and procedures by the director of the laundry service is deleted.

At N.J.A.C. 8:43G-13.10, the qualifications required of the supervisor of a hospital laundry service have been more specifically defined from “specialized training or education” to “a minimum of two years experience” in institutional laundry service.

At N.J.A.C. 8:43G-13.11(a) amended language requires all laundry (as opposed to the current requirement of soiled laundry) removed from patient rooms and other service areas to be transported so that no leakage occurs. In addition, bedding and clothing provided to staff and patients are now required to be not only clean, but also “in good repair.” (N.J.A.C. 8:43G-13.11(d))

N.J.A.C. 8:43G-13.13(a) adds amended language that now requires an adequate supply of laundered items (rather than the previous standard of three times the number of occupied beds), requires these items to be in good repair and also adds scrub suits to the list of required laundry items. A new paragraph (N.J.A.C. 8:43G-13.13(a)1) requires hospitals to supply laundered scrub suits in surgical suites, obstetrical surgical suites, postanesthesia care units, central supply and other areas as determined by hospital policy. N.J.A.C. 8:43G-13.13(c) now requires the retention of monitoring data for linen supply, stained linens, unsafe objects found and pH levels.

N.J.A.C. 8:43G-13.16 and 13.17 are new sections requiring written sanitation policies and procedures, and a director/supervisor of sanitation “with specialized training or education” in institutional sanitation. This individual may be a consultant.

N.J.A.C. 8:43G-13.18 through 13.26 have been relocated nearly word for word from N.J.A.C. 8:43G-14.9 through 14.16 of the existing Licensing Standards for Hospitals. They are not new additions to the licensing standards with the exception of the hot water temperature standard, which has been raised from the previous standard (that is, 95 to 110 degrees Fahrenheit) to the standard now recommended by the American Institute of Architects (AIA) “Guidelines for Design and Construction of Hospital and Health Care Facilities, 2001 Edition” 1735 New York Avenue, Washington, DC 20006 (that is, 105 to 120 degrees Fahrenheit or 41 to 49 degrees Celsius as set forth in AIA guideline A7.31.E3.) to prevent Legionella and other waterborne pathogens.

Subchapter 14 Infection Control

N.J.A.C. 8:43G-14.1 has been expanded to establish an infection control program headed by a hospital epidemiologist, to oversee and direct the hospital’s infection control activities. The hospital epidemiologist must be a board-certified physician with additional training in infection control. The infection control program, as distinct from the infection control committee under the current standards, has the primary responsibility for the direction of all of the hospital’s infection control efforts. The infection control program consists of the hospital epidemiologist, infection control professionals, a clinical microbiologist, and a pharmacist. The hospital epidemiologist is also chairperson of the infection control committee, which under the current standards directs infection control

activities. In the amended rule, the membership of the infection control committee has been broadened to include representatives from several hospital departments that were not previously included.

These organizational changes place the ultimate responsibility for hospital infection control activity within a smaller group with a higher level of professional education and training. The group, the Infection Control Program (ICP), oversees and works with the Infection Control Committee.

At proposed N.J.A.C. 8:43G-14.1(d)1 through 6 (recodified current (b)), the activities/responsibilities of the ICP with respect to surveillance and infection prevention and control are described in specific detail.

A total of nine Centers for Disease Control published guidelines and Hospital Infection Practices Advisory Committee (HICPAC) recommendations are incorporated by reference as amended and supplemented at N.J.A.C. 8:43G-14.1(d)1iii. These nine publications can be summarized as follows:

1. Guideline for Prevention of Catheter Associated Urinary Tract Infections. This publication contains current CDC recommendations for prevention of urinary tract infections by proper management of temporary indwelling urethral catheters. (N.J.A.C. 8:43G-14.1(d)1iii(1))

2. Guideline for Prevention of Intravascular Device-related Infections. This guideline is designed to reduce the incidence of intravascular device-related infections by providing recommendations considered prudent by the Hospital Infection Control Practices Advisory Committee (HICPAC) for the use and maintenance of intravascular devices. (N.J.A.C. 8:43G-14.1(d)1iii(2))

3. Guideline for Prevention of Surgical Site Infection, 1999. This document presents the Centers for Disease Control and Prevention (CDC's) recommendations for prevention of surgical site infections. The document is primarily intended for use by surgeons, operating room nurses, infection control professionals, and other personnel directly responsible for prevention of nosocomial infections. (N.J.A.C. 8:43G-14.1(d)1iii(3))

4. Guidelines for Prevention of Nosocomial Pneumonia. These recommendations, intended for use by personnel who are responsible for surveillance and control of infections in acute-care hospitals, addresses common problems encountered by infection control practitioners regarding the prevention and control of nosocomial pneumonia in hospitals. (N.J.A.C. 8:43G-14.1(d)1iii(4))

5. Guideline for Handwashing and Hospital Environmental Control, 1985. Provides CDC recommendations for handwashing, as well as for cleaning and disinfecting a hospital's inanimate environment. (N.J.A.C. 8:43G-14.1(d)1iii(5))

6. Guideline for Infection Control in Hospital Personnel (1998).
   This guideline updates the CDC guideline of the same title from 1983. The revisions focus on the epidemiology of infections known to be transmitted in health care settings, and on methods for reducing the transmission of infections from patients to health care personnel and from personnel to patients. (N.J.A.C. 8:43G-14.1(d)1iii(6))

7. Guideline for Isolation Precautions in Hospitals (1996).
   HICPAC and CDC have revised this guideline to assist hospitals in maintaining up-to-date isolation practices. (N.J.A.C. 8:43G-14.1(d)1iii(7))

8. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Facilities, (MMWR 1994). Replaces and updates all previously published guidelines for prevention of *Mycobacterium tuberculosis* in health care facilities. (N.J.A.C. 8:43G-14.1(d)1iii(8))

9. HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance, (1995). Since 1989, a rapid increase in the incidence of infection by vancomycin-resistant enterococci (VRE) has been reported by US hospitals. This report presents recommendations of HICPAC for preventing and controlling the spread of vancomycin resistance, with a special focus on VRE. (N.J.A.C. 8:43G-14.1(d)1iii(9))

In an effort to have licensing standards reflect current practice and knowledge, note that two CDC websites are listed at N.J.A.C. 8:43G-14.1(d)1 along with traditional CDC Guidelines and medical journals. New language at N.J.A.C. 8:43G-14.1(d)2 cites updated OSHA/CDC requirements for universal precautions. These rules are also incorporated therein by reference, as amended and supplemented. Briefly summarized, OSHA's Blood Borne Pathogens Regulation, (29 CFR 1910.1030), requires employers to establish written control plans to eliminate or minimize employee exposures to pathogenic microorganisms that are present in human blood and can cause disease in humans. This standard addresses handling, transport, labeling, and decontamination of reusable medical instruments contaminated with blood or body fluids. (N.J.A.C. 8:43G-14.1(d)2)

At N.J.A.C. 8:43G-14.1(d)3: the reference added in parenthesis to N.J.A.C. 8:43G-13, Housekeeping, Laundry, and Sanitation, reflects the fact that all of the sections in Subchapter 14 on sanitation and waste disposal have been moved to Subchapter 13, currently Housekeeping and Laundry, to better organize the standards.

N.J.A.C. 8:43G-14.1(d)4 (current (b)5) is amended consistent with changes made to N.J.A.C. 8:43G in December 1999, that general infection control policies and procedures must be reviewed not annually, but every three years or more often as necessary, while other areas of greater immediacy must be reviewed at least annually. The infection control measures or studies requirement as previously set forth at N.J.A.C. 8:43G-14.1(b)4 is deleted and replaced by requirements at N.J.A.C. 8:43G-14.1(d)1.

N.J.A.C. 8:43G-14.1(d)6 concerning reporting of HIV/AIDS has been added to the responsibilities of the ICP.

N.J.A.C. 8:43G-14.1(e) (current (c)) is amended to shift responsibility for sharing information with other hospital programs from the current infection control committee to the infection control program. Note that here and throughout this subchapter and all of the proposed amendments to infection control standards, any reference to "quality assurance" has been changed to "quality improvement." This is consistent with changes made in the revision to N.J.A.C. 8:43G on December 20, 1999. In addition, amended language at N.J.A.C. 8:43G-14.1(f) changes the meeting schedule for the infection control committee from once every two months to six times per year with at least one meeting per quarter.

N.J.A.C. 8:43G-14.1(g) (current (e)) is amended to assign responsibility for hospital infection control policies/procedures to the hospital epidemiologist as well as the infection control professional.

N.J.A.C. 8:43G-14.3 is amended to add the requirement that the infection control professional/practitioner become certified in infection control within five years, and maintain the certification through the Certification Board of Infection Control (CBIC). As with other more specific amendments to these rules, this amendment is intended to improve the quality of infection control practice.

N.J.A.C. 8:43G-14.5(b) is amended to increase the ratio of infection control professional to beds from one infection control professional per 250 occupied beds to one infection control professional per 200 adjusted occupied beds, where the occupancy rate has been adjusted by both an outpatient factor and by the hospital's case mix index. As in the current rules, all hospitals must maintain a minimum of at least one half-time infection control professional.

N.J.A.C. 8:43G-14.5(c) is added to extend the hospital's responsibility for infection control to off-site affiliated facilities.

N.J.A.C. 8:43G-14.6(b) (current 14.7(b)) and 14.7 (current 14.8) are amended to change "infection control practitioner" to "infection control professional," and "quality assurance" to "quality improvement." The infection control patient services, previously contained in N.J.A.C. 8:43G-14.6 are recodified as part of the CDC guidelines adopted by reference as set forth at N.J.A.C. 8:43G-14.1(d)1ii(1) through (5).

N.J.A.C. 8:43G-14.7 is amended to refer to infection control "professional" rather than "practitioner." In addition, language is added to clarify that quality improvement activity oversight is the responsibility of the continuous quality improvement program.

N.J.A.C. 8:43G-14.9, Sanitation patient services, through 14.16, Solid waste supplies and equipment, have all relocated to Subchapter 13, Housekeeping, Laundry and Sanitation.

Subchapter 20 Employee Health

N.J.A.C. 8:43G-20.2(d) is amended to require that not only physician employees, but also any member of the medical staff with privileges to practice in the facility receive a Mantoux tuberculin skin test. The protocols for Mantoux tuberculin testing have also been updated to be consistent with current guidelines from the Centers for Disease Control (CDC). The CDC guidelines are incorporated by reference, as amended and supplemented. The purpose of these guidelines is to emphasize the importance of : a) a hierarchy of control measures, including administrative and engineering controls and personal respiratory protection; b) the use of risk assessments for developing a TB control plan; c) early identification and management of persons who have TB; d) TB screening programs for health care workers (HCW); e) HCW training and education; and f) evaluation of TB infection-control programs. Amendments to this section also outline the frequency of subsequent Mantoux testing, as determined by an annual tuberculosis risk assessment of the facility.

Subchapter 24 Plant Maintenance and Fire and Emergency Preparedness

N.J.A.C. 8:43G-24.8 is amended to delete the specific reference to the 1987 American Institute of Architects hospital construction guideline text reference (at N.J.A.C. 8:43G-24.8(a)) and replace it with the most recent AIA guideline publication (2001), as amended and supplemented. This amended reference language is consistent with language in the ambulatory care facility licensing rules as set forth at N.J.A.C. 8:43A-19.1(a). In addition, amended language is added at N.J.A.C. 8:43G-24.8(b), that corrects the name and location of the architectural plans review program, now located within the Department of Community Affairs.

N.J.A.C. 8:43G-24.9 is a new section requiring health care facilities to assess the potential impact on infection control of any construction or renovation contemplated by the facility, and to address the risk before, during, and at completion of the project.

Because a 60-day comment period has been provided on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Department's licensing standards establish the minimum standards of care for all New Jersey licensed health care facilities. The proposed infection control amendments, new rules and repeals reflect a commitment by the Department to be responsive to a changing health care environment and technology, and to protect the quality of care by ensuring that licensing standards reflect current theory and practice. The Department anticipates that the social impact will be favorable, since the proposed amendments, new rules and repeals, if adopted and followed, should have the effect of reducing the incidence of nosocomial infection in licensed New Jersey health care facilities.

Economic Impact

In some respects the proposed amendments, new rules and repeals are less restrictive than current rules. Throughout these proposed amendments, new rules and repeals, for example, consistent with changes to N.J.A.C. 8:43G adopted December 20, 1999, the requirement that written policies and procedures be revised and updated annually has been changed to every three years. This will be less burdensome to all licensed facilities, and recognizes both that staff in health care facilities are generally too busy to spend time revising policies every year, and that it is not necessary because patterns of care do not change fast enough to justify it. This relaxation of timeframes should free up staff time for more urgent matters, and may thereby have a positive economic impact on New Jersey's health care facilities.

In some instances, however, health care facilities will have to expend additional time and money to comply with the proposed standards. Hospitals will be required under the proposed standards to employ a hospital epidemiologist who is a board-certified physician with specific training and/or experience in infection control practices or hospital epidemiology. This requirement for more specialized education and training may require higher salaries. In addition, the ratio of infection control professionals to hospital beds will change from one infection control practitioner per 250 occupied beds to one infection control professional per 200 "adjusted occupied beds," as defined below. This particular change, however, should have little financial impact, as most inpatient facilities are already staffed at this level or above.

However, it is the intent and purpose of the proposed amendments, new rules and repeals that such up-front and quantifiable additional expenses will result in a decrease in nosocomial infection, and thereby generate larger though less quantifiable savings, both to the health care facilities involved and to society in general.

Federal Standards Statement

The Federal standards governing acute care hospitals are contained within Chapter IV: Health Care Financing Authority; Subchapter E: Standards and Certification; 42 C.F.R. Part 452, Conditions of Participation for Hospitals in relation to New Jersey licensing standards for hospitals. Those Federal Conditions of Participation are used as a survey mechanism for selected hospitals participating as providers in the Medicare and Medicaid programs. In general, the Conditions of Participation are not comprehensive and have not been updated since 1991. Accordingly, the proposed amendments, new rules and repeals to N.J.A.C. 8:43G do not impose standards on hospitals that exceed those contained in applicable Federal standards.

Jobs Impact

The proposed amendments, new rules and repeals will not result in any loss of jobs in the healthcare industry or elsewhere. They may result in some moderate increase in infection control staffing in healthcare facilities.

Agriculture Industry Impact

The proposed amendments, new rules, and repeals will have no impact on the agriculture industry.

Regulatory Flexibility Statement

The proposed amendments, new rules and repeals affect New Jersey hospitals, all of which employ well over 100 full-time employees. Thus, they are not defined as small businesses within the definition of that term, as set forth in N.J.S.A. 52:14B-15 et seq., and no regulatory flexibility analysis is necessary.

Smart Growth Impact

The proposed amendments, new rules and repeals will have no impact upon the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

Full text of the proposed repeals may be found in the New Jersey Administrative Code at N.J.A.C. 8:43G-8.9, 8.12, 8.13, 14.6, and 14.9 through 14.16.

Full text of the proposed amendments and new rules follows (additions indicated in boldface **thus;** deletions indicated in brackets [thus]:

8:43G-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"All payers case mix index" (CMI) means a specific hospital's average charge per case divided by the Statewide average charge per case for a given year using the most recent complete data set available to the Department.

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SUBCHAPTER 8 CENTRAL [SUPPLY] SERVICE

8:43G-8.1 Central [supply] service policies and procedures

(a) The hospital's central **[**supply**]** service shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. These policies and procedures shall be approved by the hospital's infection control committee.

(b) Policies and procedures for central **[**supply**]** **service** shall include at least decontamination and **[**sterile**]** **sterilization** activities, including receiving, decontamination, storage, cleaning, packaging, disinfection, sterilization, and distribution of reusable items.

(c) All equipment and instruments in the hospital shall be processed according to central **[**supply**]** **service** cleaning and sterilization policies and procedures.

(d) Manufacturers' **written** recommendations for equipment use, testing, and cleaning shall be readily available in central **[**supply**]** service**[**s**]** and in the department where the equipment is used.

(e) Methods for processing reusable medical devices shall conform with the following or revised or later editions, if in effect, incorporated herein by reference:

1. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Good Hospital Practice: Steam Sterilization and Sterility Assurance." ST 46;

2. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use." ST 37;

3. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Safe Use and Handling of Gultaraldehyde-based Products in Health Care Facilities." ST 58;

4. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Guidelines for the Selection and use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities." ST 33;

5. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Steam Sterilization and Sterility Assurance Using Table Top Sterilizers in Office-Based, Ambulatory Care, Medical, Surgical and Dental Facilities," January 1998, ST 42R;

6. Society of Gastroenterology Nurses and Associates, Inc., "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes" (2000);

7. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings," ST 35; and

8. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness," October 1998, ST 41R.

(f) The documents referenced in (e) above are reviewed and/or revised every five years or more frequently as needed; the most current document is to be used. The AAMI requirements can be obtained from: The Association for the Advancement of Medical Instrumentation, 3330 Washington Building, Suite 400, Arlington, VA 22209 or at the AAMI website at www.aami.org. SGNA's Standards and Guidelines are available from the Society of Gastroenterology Nurses and Associates, Inc., 401 North Michigan Ave., Chicago, Il 60611-4267, or at www.sgna.org.

8:43G-8.2 Central [supply] service staff qualifications

(a) There shall be a full-time director or supervisor of central **[**supply**]** service**[**s**]**.

(b) **[**By January 1, 1991, the director or supervisor of central supply service shall have received a certificate for completing a central service training course recognized by the Department of Health.**]** **The director or supervisor of central services shall have two years of supervisory experience and shall be certified through a national sterile processing program recognized by the New Jersey Department of Health and Senior Services.**

(c) All personnel involved in sterile processing shall be certified through a national sterile processing program recognized by the New Jersey Department of Health and Senior Services within three years of employment and (within five years of the adoption of this amendment).

(d) Personnel involved in the use of ethylene oxide shall have the appropriate licensure from the New Jersey Department of Environmental Protection.

8:43G-8.3 [(Reserved)] Central service staff education and training

(a) Requirements for the central service education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) All new central service employees shall receive on-the-job training on practices and equipment unique to the hospital.

(c) Competency for processing tasks shall be documented annually by the employee's supervisor or by the Director of Central Services.

8:43G-8.4 Central [supply] service patient services

(a) Entrance to the central **[**supply**]** **service** processing and decontamination area shall be restricted to persons attired in hospital-laundered or protective attire, in relation to the purpose and scope of their duties.

1. All personnel performing decontamination, preparation, and assembly shall be provided hospital laundered scrubs.

(b) All reusable patient care items shall be reprocessed according to manufacturers' **written** recommendations.

(c) There shall be a preventive maintenance program for all patient care equipment processed by central **[**supply**]** **service** that includes performance verification records. Preventive maintenance shall be documented **and records shall be available for inspection**.

(d) **[**All patient care equipment shall be cleaned, disinfected, or sterilized. according to the use of the item.**]** **Sterile supplies which bear an expiration date shall not exceed the shelf life date as recommended by the manufacturer of the packaging and/or of the device contained.**

1. Muslin blends shall not exceed a shelf life of 30 days.

2. A policy and procedure to retrieve and reprocess outdates shall be established and enforced.

[(e) Shelf life of packaged sterile items shall be determined and indicated on the items according to central supply sterilization policies and procedures which follow guidelines recommended by the Association for the Advancement of Medical Instrumentation (AAMI) as outlined in "Good Practice: Steam Sterilization and Sterility Assurance," incorporated herein by reference.

Note: AAMI requirements can be obtained from:

The Association for the Advancement of Medical Instrumentation
Suite 602
1901 North Fort Myer Drive
Arlington, VA 22209

(f) Single-use items shall be reused or reprocessed only if the manufacturer recommends reuse or reprocessing, or if the hospital has scientific validation of the safety of reprocessing and reuse of the item. Procedures for reprocessing and reuse shall conform

with these recommendations or validation studies.**]** **(e) If the facility is using an Event Related Sterility program, the process shall:**

1. Be approved by the Hospital Infection Control Committee;

2. Have a continuous process improvement plan with monthly audits and documentation of facility compliance including:

i. Proper transportation of sterile product;

ii. Proper storage conditions of sterile product;

iii. Proper rotation of sterile product; and

iv. Maintenance of sterile pack integrity; and

3. Include annual inservice education as part of mandatory Infection Control inservicing.

8:43G-8.5 [(Reserved)] Single use medical devices and outsourcing

(a) Single use patient care items shall not be reprocessed except under the following conditions:

1. The manufacturer provides written instruction for cleaning and sterilization of the item and the facility has the resources to meet those specifications; and/or

2. Methods for processing single use patient care items conform with the following Food and Drug Administration regulations:

i. Premarket notification, registration and listing shall comply with Title 21 CFR, Part 807, incorporated herein by reference, as amended and supplemented; and

ii. Quality system regulations shall be as specified in 21 CFR Part 807, incorporated herein by reference, as amended and supplemented; and

3. A quality control program shall be established to ensure the delivery of a safe product as specified in the contract with the third party processor.

(b) Policies and procedures shall be established following OSHA's Blood Borne Pathogens regulation, 29 CFR § 1910.1030, incorporated herein by reference, as amended and supplemented, for the transport of contaminated equipment to off site reprocessing facilities.

(c) Shared reprocessing by multi-hospital reprocessing centers shall meet the following standards:

1. Policies and procedures for all processing protocols shall be approved by all facilities in the network in conjunction with infection control and all sterile processing managers.

2. Instruments and devices transported off site for processing shall be inventoried and pre-cleaned prior to transportation.

3. All decontamination, assembly and sterilization shall be performed according to the device manufacturer's written recommendations.

4. The following records shall be maintained at the processing facility:

i. Sterilization logs shall be maintained for all items sterilized; and

ii. Biological monitoring as specified in N.J.A.C. 8:43G-8.8(a).

(1) Immediate notification shall be made to the receiving hospital upon a positive biological result.

5. Transport of sterile product shall be performed using disinfected, impervious containers that are either locked or sealed in covered carts.

8:43G-8.6 Central [supply] service space and environment.

(a) **[**Sterile supplies shall be processed, packaged, rotated, distributed stored, and dated in such a way as to ensure the integrity and sterility of the sterile item.**]** **Each sterilizer processing area shall have exhaust ventilation to remove heat, moisture and odors without recirculating the exhaust to other areas of the hospital.**

(b) – (c) (No change.)

(d) All work surfaces in central supply shall be cleaned with germicidal disinfectant at the end of each work shift **and more frequently as necessary**.

(e) (No change.)

8:43G-8.7 [Central supply supplies and equipment] Use and sterilization of patient care items

(a) [An illuminated worktable shall be provided to examine linen used for wrapping sterile supplies for tears, pinholes, and other defects.] **Patient care items shall be scrupulously cleaned prior to sterilization or disinfection. The selection and use of**

disinfection and/or sterilization methods for patient care items or equipment shall be divided into the following three categories:

1. Critical items are objects that enter sterile tissue or the vascular system. These instruments other than scopes must be sterilized by a process that can demonstrate a sterility assurance level of 10^{-6}.

2. Semicritical items are objects which come into contact with mucous membranes or with skin that is not intact. Semicritical items require high level disinfection or intermediate level disinfection. (At a minimum, the disinfectant must be labeled as tuberculocidal.)

3. Noncritical items are objects that come in contact with intact skin, but not with mucous membranes. Noncritical items require intermediate level disinfection or low level disinfection.

(b) Laparoscopes, arthroscopes, and other scopes that enter normally sterile areas of the body shall be sterilized or given high-level disinfection after each use according to manufacturers' **written** recommendations or according to policy established by the hospital's infection control committee.

(c) [Scopes and all channels that enter non-sterile areas of the body shall be given high level disinfection after each use according to the manufacturers' recommendations or according to hospital policy.] **Reusable linens shall be inspected and delinted in a segregated room with adequate ventilation to prevent excess dust and lint accumulation.**

1. An illuminated worktable shall be provided to examine linen used for wrapping sterile supplies for tears, pinholes, and other defects.

2. Reusable linens shall be repaired using a heat patch machine.

(d) [Accessories, to scopes shall be sterilized or processed according to manufacturers' recommendations after each use.] **Flash sterilization and peracetic acid processes are considered just in time sterilization processes. ("Just in time" means for immediate use only.)**

1. Flash sterilization should be used for emergency situations only.

2. All items that are flash sterilized shall be thoroughly cleaned and decontaminated prior to sterilization.

3. All items in each flash sterilization cycle shall be documented.

(e) (No change.)

(f) There shall be a system for monitoring the processing of all equipment and instruments in the hospital for adherence to central [supply] **service** policies and procedures.

8:43G-8.8 [(Reserved)] Monitoring the sterilization cycle

(a) Biological monitoring with live spores, or an FDA approved equivalent, shall be performed as follows:

1. Ethylene oxide - in each load;

2. Peracetic acid – weekly;

3. Low temperature gas plasma - daily in the working load; and

4. Steam sterilizers - weekly.

(b) The biological indicator shall be applicable for the sterilization process used and be stored and used in accordance with the manufacturer's recommendations.

(c) A biological monitor with live spores shall be performed following repair or breakdown of the equipment in (a) above..

(d) A biological monitor, or spore based enzyme, shall be used with each load containing implantables and the implantable shall not be used until the negative biological test is received.

(e) A chemical indicator/integrator, applicable to the sterilization process used, shall be used in the following:

1. Each package processed in steam;

2. Each package processed in ethylene oxide;

3. Each package processed in low temperature gas plasma;

4. Each load as directed by the manufacturer for peracetic acid; and

5. A prevacuum air removal test shall be performed daily on each prevacuum sterilizer and following repair or breakdown of the prevacuum sterilizer.

(f) In the event of positive biological test results on a sterilizer, effective corrective action shall be taken including retesting and recalls if indicated.

1. Documentation of actions taken shall be maintained on site.

2. There shall be an established recall system in effect.

8:43G-8.9 (Reserved)

8:43G-8.10 Central [supply] service quality [assurance] improvement methods

There shall be a program of quality [assurance] **improvement** for central [supply] **service** that is integrated into the hospital quality [assurance] **improvement** program and includes regularly collecting and analyzing data to help identify health service problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data.

8:43G-8.11 Sterilizer patient services

(a) (No change.)

(b) [Before they are sterilizer processed, all] **All** instruments and equipment shall be visually inspected for cracks, pitting, rust, or any condition that would impede cleaning/sterilization. **Defective instruments and equipment shall not be used.**

(c) Sterilizers in use shall be [kept] cleaned **on a scheduled basis**.

(d) –(e) (No change.)

[(f) Methods for processing reusable medical devices shall conform with the following or revised or later editions, if in effect, incorporated herein by reference:

1. The current edition of the Centers for Disease Control "Methods for Assuring Adequate Processing and Safe Use of Medical Devices";

2. The Association for the Advancement of Medical Instrumentation, (AAMI) requirements, "Good Hospital Practice: Steam Sterilization and Sterility Assurance," and

3. The Association for the Advancement of Medical Instrumentation, (AAMI) requirements, "Good Hospital Practice: Steam Sterilization Using the Unwrapped Method (Flash Sterilization)."]

(f) A record of each sterilization/disinfection load, including the date, load/cycle number and the specific contents of the load shall be retained for a least one year or per hospital policy whichever is greater.

(g) (No change.)

(h) An indicating thermometer, accurate to three degrees Fahrenheit, shall be located in all ethylene oxide aeration equipment.

(i) All sterilizers shall be operated and maintained in accordance with the manufacturer's instructions.

8:43G-8.12 and 8:43G-8.13 (Reserved)

SUBCHAPTER 13. HOUSEKEEPING, [AND] LAUNDRY, and Sanitation

8:43G-13.1 Housekeeping policies and procedures

(a) – (b) (No change.)

(c) There shall be a list available at all times of all cleaning and disinfecting agents used in the hospital together with **[**a list of**]** their **[**antidotes**]** **Materials Safety Data Sheet (MSDS)**.

(d) Records of all pesticides and herbicides used at the hospital shall be maintained on-site, together with **[**a description of**]** their **[**antidotes**]** **Materials Safety Data Sheet (MSDS)**.

(e) All cleaning and disinfecting agents shall be correctly labeled with the name of the product and its use, **as specified by the manufacturer,** including agents that have been repackaged from a bulk source.

(f) All pesticides shall be applied in accordance with State Pesticide Control Code, N.J.A.C. 7:30.

8:43G-13.4 Housekeeping patient services

(a) – (b) (No change.)

(c) Reusable hand-cleanser dispensers shall be clean inside and out. Disposable dispensers shall be discarded **and not refilled**.

(d) – (l) (No change.)

(m) Housekeeping and cleaning supplies shall be selected **[**,**]** **and approved by the Infection Control Committee. They shall be** measured **[**,**]** and used correctly and according to manufacturers' **written** instructions.

(n) – (o) (No change.)

(p) [Buildings] **Periodic documented inspections of buildings** and grounds shall be **[**inspected periodically by the director of housekeeping or a designee and**]** **performed. Buildings and grounds shall be** maintained in a clean and safe condition.

(q) Articles in storage shall be elevated from the floor and away from walls, ceilings, and air vents to facilitate cleaning. Storage units shall be non-porous and cleanable.

(r) All communal toys shall be washed daily or more frequently as needed. No stuffed animals shall be allowed except for personal use.

(s) Plants and flowers shall not be allowed in patient treatment areas (such as operating rooms and procedure rooms) or sterile processing areas.

8:43G-13.5 Housekeeping supplies and equipment

(a) – (c) (No change.)

(d) When not in use, cleaning and disinfecting agents shall be stored **on** separate **shelves** from other supplies and in enclosed areas.

[(e) Cleaning agents used in the hospital shall be approved by the housekeeping service and the infection control committee.**]**

8:43G-13.8 Housekeeping quality [assurance] improvement methods

(a) There shall be a program of quality **[**assurance**]** **improvement** for housekeeping that is coordinated with the hospital quality **[**assurance**]** **improvement** program and includes collecting and analyzing data to help identify problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data. **(See N.J.A.C. 8:43G- 27, Continuous Quality Improvement)**

(b) Hospitals that contract with a commercial housekeeping service shall use quality **[**assurance**]** **improvement** measures to ensure that the same standards are met as apply to an in-house housekeeping service.

8:43G-13.9 Laundry policies and procedures

(a) The laundry service shall have written policies and procedures, which are reviewed **[**annually**]** **every three years or more frequently as needed**, revised as needed, implemented, and followed, and which include at least a policy that identifies special handling practices for soiled laundry. **These policies and procedures shall be approved by the hospital's infection control committee.**

(b) **[**Contaminated**]** **All used** laundry shall be **considered contaminated and** **[**specially**]** handled according to the hospital's written **[**protocol**]** **policies and procedures**, which are approved by the infection control committee **[**and the director of the laundry service**]**.

8:43G-13.10 Laundry staff qualifications

There shall be a designated director or supervisor of laundry with **[**specialized training or education in institutional laundry service**]** **a minimum of two years of experience in institutional laundry service**.

8:43G-13.11 Laundry patient services

(a) All **[**soiled**]** laundry from patient rooms and other service areas shall be transported in such a way that no leakage occurs.

(b) – (c) (No change.)

(d) Bedding (sheets, pillowcases, drawsheets, and blankets) and clothing provided to staff and patients shall be clean **and in good repair**.

8:43G-13.13 Laundry supplies and equipment

(a) The hospital shall have on-site **[**a**]** **an adequate** supply of sheets, **in good repair,** pillowcases, drawsheets, blankets, towels, **[**and**]** washcloths**, and scrub suits** **[**that is at least three times the number of occupied beds**]**.

1. All hospitals shall provide laundered scrub suits in the following areas: surgical suites, obstetrical surgical suites, postanesthesia care unit, central services, and those areas as determined by hospital policy.

(b) (No change.)

(c) The laundry service shall monitor**, and retain documentation for one year,** at least the following:

[1. pH;**]**

[2.**]** **1.** Unsafe objects found;

[3.**]** **2.** Linen supply; **[**and**]**

[4.**]** **3.** Stained linens**[**.**]****; and**

[(d)**]** **4. pH.** A random sample of all laundry batches from all sources shall be sour tested to ensure neutralization of alkaline residues from built detergents. Sour testing is a test performed to indicate the degree of acidity or alkalinity of linens. Built detergents are

a mixture of one or more alkaline detergents that contains not less than 50 percent anhydrous soap (pure soap, free from water). Fabric pH shall be maintained at 7.0 or below after souring when built detergents are used.

8:43G-13.15 Laundry continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for the laundry service that is coordinated into the hospital continuous quality improvement program and includes regularly collecting and analyzing data to help identify problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data. **(See N.J.A.C. 8:43G-27, Continuous Quality Improvement).**

(b) (No change.)

8:43G-13.16 Sanitation policies and procedures

The sanitation service shall have written policies and procedures that are reviewed every three years, revised as needed, and implemented. They include, at least, scope of responsibility, assignment by designated unit, and responsibility for all sanitation tasks.

8;43G-13.17 Sanitation staff qualifications

There shall be a designated director or supervisor of sanitation with specialized training or education in institutional sanitation service. A consultant may be used to fulfill this role.

8:43G-13.18 Sanitation patient services

(a) The water supply shall be adequate in quantity, of a safe sanitary quality, and from a water system that is constructed, protected, operated, and maintained in conformance with the New Jersey Safe Drinking Water Act, N.J.S.A 58:12A-1 et seq. and N.J.A.C. 7:10 and other applicable laws, ordinances, and regulations.

1. The Safe Drinking Water Act and rules can be obtained from:

The New Jersey Department of Environmental Protection
Bureau of Potable Water
P.O. Box 209
Trenton, NJ 08625

(b) Hot running water (between 105 and 120 degrees Fahrenheit or 41 to 49 degrees Celsius) and cold running water shall be provided in patient care areas.

8:43G-13.19 Sanitation space and environment

(a) Water piping carrying non-potable water shall be clearly labeled as such.

(b) The sewage disposal system shall be maintained in good repair and operated in compliance with State and local laws, ordinances, and regulations.

(c) There shall be no direct physical connections between city and well water supplies. Any physical connection between a public community water supply and an unapproved water supply, such as a well used by a hospital for emergency purposes, must be approved by the New Jersey Department of Environmental Protection and the owner of the public community water supply and must conform with N.J.A.C. 7:10-10.

(d) There shall be no back siphonage conditions present.

(e) Equipment requiring water drainage, such as ice machines, shall be drained to a sanitary connection in a way that avoids splatter or overflow.

8:43G-13.20 Sanitation quality improvement methods

The hospital shall adhere to the water sampling schedule and the chemical and biological monitoring requirements of the water supply system set by the New Jersey Department of Environmental Protection. Records of the sampling and monitoring shall be maintained.

8:43G-13.21 Regulated medical waste policies and procedures

(a) The hospital shall develop and implement and the Infection Control Program shall review, approve, and audit written policies and procedures for collection, storage, handling, transport and disposal transport of medical waste, in conformance with applicable Federal and State laws and regulations.

(b) The hospital shall comply with the provisions of 42 U.S.C. § 6903, the Medical Waste Tracking Act of 1988 and N.J.S.A 13:1E-48 et seq., the Comprehensive Regulated Medical Waste Management Act and all rules and regulations promulgated pursuant to the aforementioned Acts.

8:43G-13.22 Regulated medical waste and solid waste management

(a) Policies and procedures for solid waste and recyclables shall be established and enforced to ensure appropriate collection, storage and disposal and to maintain them clean and odor-free and to prevent the breeding of insects or vermin.

(b) Solid waste shall be stored within the containers provided for it in an area that is kept clean. Waste shall be collected from storage area regularly to prevent nuisances such as odors, flies, other vermin, or rodents, and so that waste does not overflow or accumulate beyond the capacity of the storage containers.

(c) Plastic bags shall be used for solid waste removal from patient care units and supporting departments. Bags shall be of sufficient strength to safely contain waste from point of origin to point of disposal and shall be effectively closed prior to disposal.

(d) Garbage compactors shall be located on an impervious pad that is graded to a drain. The drain shall be kept clean and shall be connected to the sanitary sewage disposal system.

(e) Outside storage containers for solid waste shall be kept covered, except those used for corrugated cardboard, recyclables, or construction materials.

SUBCHAPTER 14. INFECTION CONTROL [AND SANITATION]

8:43G-14.1 Infection control program structural organization

(a) A hospital epidemiologist shall direct and oversee the hospital Infection Control Program. A hospital epidemiologist is defined as a physician who is board certified in a medical specialty, preferably Infectious Diseases, and has training (such as a Centers for Disease Control and Prevention Course, or Society for Healthcare Epidemiology of America (SHEA) course, or a Master's Degree in Public Health) or at least five years experience in hospital epidemiology. The hospital epidemiologist may be a consultant.

(b) A hospital Infection Control Program shall be multi-disciplinary and include a hospital epidemiologist, infection control professional(s), a clinical microbiologist, and a pharmacist. In addition, the program shall have an on-going surveillance system to monitor nosocomial infections, antimicrobial resistance, antimicrobial use, and outbreaks of infectious diseases.

[(a)**]** **(c)** There shall be a hospital infection control committee that includes representatives from at least: infection control, medical staff, nursing service, **dietary,** administration, clinical **[**laboratory**]** **microbiology**, respiratory care services, **[**surgery**]** **surgical services, central services, environmental services, pharmacy**, and the employee health service. **The chairman of the committee shall be the hospital epidemiologist.** The committee shall **participate in the hospital's overall quality improvement program and shall** receive formal advice from all other services upon its request.

[(b)**]** **(d)** The infection control **[**committee**]** **program** shall **[**direct and assure compliance with the infection control program, including at least the following**]** **oversee, but not be limited to, the following activities**:

1. Formulating a system for **[**identifying and monitoring**]** **surveillance, prevention, and control of** nosocomial infections **[**that is at least equivalent to the Centers for Disease Control "Definitions for Nosocomial Infections, 1988", PB88-187117, and CDC Guidelines for Isolation Precautions in Hospitals incorporated herein by reference**]**.

i. Surveillance: Surveillance of nosocomial infections shall be performed. The surveillance process shall include at least the following elements:

(1) Identification and description of the problem or event to be studied;

(2) Definition of the population at risk;

(3) Selection of appropriate methods of measurements, including statistical tools and risk stratification;

(4) Identification and description of data sources and data collection personnel and methods;

(5) Definitions of numerators and denominators;

(6) Preparation and distribution of reports to appropriate groups; and

(7) Selection of specific events to be monitored and guided by validated, available benchmarks and appropriately adjusted for patient risks so that meaningful comparisons can be made.

ii. Rates are calculated from the above surveillance monitoring for internal quality improvement activities.

iii. Prevention and control: Activities shall be based on Centers for Disease Control and Prevention published guidelines and Hospital Infection Control Practices Advisory Committee (that is, HICPAC) recommendations. An exception to the adoption of the following guidelines shall be allowed providing that there is a sound infection control rationale based upon scientific research or epidemiologic data. The following published guidelines and recommendations are incorporated herein by reference, as amended and supplemented:

(1) Guideline for Prevention of Catheter-Associated Urinary Tract Infections (1981);

(2) Guideline for Prevention of Intravascular Device-Related Infections (Infection Control and Hospital Epidemiology 1996; 17: 438-73 and American Journal of Infection Control 996; 24: 262-93);

(3) Guidelines for Prevention of Surgical Site Infections (1999) (Infection Control and Hospital Epidemiology 1999; 20:247-278);

(4) Guideline for Prevention and Control of Nosocomial Pneumonia (American Journal of Infection Control, August 1994; 22:247-92 and Infection Control and Hospital Epidemiology, September 1994; 15: 587-627 and Respiratory Care, December 1994; 39: 1191-1236);

(5) Guideline for Handwashing and Hospital Environmental Control (1985);

(6) Guideline for Infection Control in Hospital Personnel (1998);

(7) Guideline for Isolation Precautions in Hospitals (Infection Control and Hospital Epidemiology 1996; 17:53-80 and the American Journal of Infection Control 1996; 24:24-52);

(8) Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Facilities (Morbidity and Mortality Weekly Report 1994; 43: 11-22); and

(9) HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance. (Infection Control and Hospital Epidemiology 1995; 16: 105-113)

iv. The guidelines listed in (d)1iii above are available from the National Technical Information Service (NTIS) by calling 703-487-4650 or writing the NTIS, 5285 Port Royal Road, Springfield, Virginia 22161. The complete set of the seven Guidelines for the Prevention and Control of Nosocomial Infections are listed under the publication number: PB86133022. Further information is available on the Centers for Disease Control and Prevention National Center of Infectious Diseases web site at: http://www.cdc.gov/ncidod/hip. The HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance is available on the CDC web site at: http://www.cdc.gov/ncidod/vancom.htm, and CDC's Hospital Infections Program's Methicillin-resistant Staphylococcus Aureus: Facts for Healthcare Workers is available at: http://www.cdc.gov/nicdod/hip/aresist/mrsahcw.htm .

2. Developing and implementing a system of infection control and isolation procedures, including Universal **(OSHA)/ Standard (CDC)** Precautions, using at least criteria which meet or exceed the criteria established by **[**the Centers for Disease Control and Prevention and Occupational Safety and Health Administration publication, "Enforcement Procedures for Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficency Virus (HIV)", OSHA Instruction CPL 2-2.44A. August 15,1988 or revised or later editions, if in effect**] 29 CFR 1910.1030, OSHA's Blood Borne Pathogens regulation incorporated herein by reference, as amended and supplemented if in effect;**

3. Reviewing and approving written policies and procedures for decontamination, disinfection, sterilization, and handling of regulated medical waste and all other solid waste **(See N.J.A.C. 8:43G-13, Housekeeping, Laundry, and Sanitation);**

[4. Instituting control measures or studies when an infection control problem is identified;**]**

[5.**]** **4.** Reviewing, **[**on at least an annual basis**]** **every three years or more frequently as necessary**, the hospital's policies and procedures related to **infection control such as**: isolation, aseptic technique, employee health, **and** staff training**[**,**]**. **Review on at least an annual basis** **[**antibiotic**]** **antimicrobial** susceptibility and trends, the prevention of infection, and general improvement of patient care; **[**and**]**

[6.**]** **5.** Identifying and reporting communicable diseases throughout the hospital, with the cooperation of the clinical laboratory, medical records, and the medical staff, as specified in N.J.A.C. 8:57-1 of "Communicable Diseases**,**"**[**,**]** also known as Chapter II of the State Sanitary Code **[**.**]** **; and**

6. Identifying and reporting of HIV/AIDS as specified in N.J.A.C. 8:57-2, Reporting of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus.

NOTE: Centers for Disease Control and Prevention publications can be obtained from:

National Technical Information Service
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161

or:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

[(c)**]** **(e)** The infection control **[**committee**]** **program, with the cooperation of the infection control committee,** shall share information, including problems, data, and relevant recommendations, with at least the quality **[**assurance**]** **improvement** program, nursing service, administration, and the medical staff, and shall ensure that corrective actions are taken.

[(d)**]** **(f)** The infection control committee shall meet at least **[**once every two months**]** **six times per year with at least one meeting per quarter**.

[(e)**]** **(g)** The **hospital epidemiologist and the** infection control **[**practitioner**]** **professional** shall participate in the development **and shall approve** of all hospital policies and procedures related to infection control.

8:43G-14.3 Infection control and hospital epidemiology staff qualifications

The infection control **[**practitioner**]** **professional** shall have education or training in surveillance, prevention, and control of nosocomial infections. **The infection control professional shall be certified in infection control within five years of beginning**

practice of infection control and shall maintain certification through the Certification Board of Infection Control (CBIC).

8:43G-14.5 Infection control staff time and availability.

(a) There shall be **[**an**]** **a hospital epidemiologist and** infection control **[**practitioner**]** **professional(s)** who **[**is**]** **are** responsible for coordination of the infection control program.

(b) There shall be a ratio of the equivalent of at least one full-time infection control **[**practitioner**]** **professional** to every **[**250**]** **200** **adjusted** occupied beds, **[**but in no case less than one half full-time equivalent, as recommended by the Centers for Disease Control and Prevention, in "The Efficacy of Infection Surveillance and Control Programs in Preventing Nosocomial Infection in U.S. Hospitals."**]** **where the bed occupancy has been adjusted both for an outpatient factor and for the hospital's all-payer case mix index (CMI), using the most recent complete data set available to the Department and the following formula:**

$$\text{Adjusted Occupied Beds} = \frac{\text{Annual Inpatient Days}}{365} \times \frac{\text{Inpatient Charges \& Outpatient Charges}}{\text{Inpatient Charges}} \times \text{All Payer CMI}$$

For every hospital, there shall be at least one half time infection control professional.

(c) Outpatient service areas provided by the hospital shall have a designated health care professional on site who is responsible for the day to day activities related to infection control.

[8:43G-14.7] 8:43G-14.6 Infection control staff education and training

(a) (No change.)

(b) The infection control **[**practitioner**]** **professional** shall coordinate educational programs to address specific problems, as recommended by the Centers for Disease Control and Prevention, or at least annually for staff in all patient care areas and services.

(c) Orientation for all new employees shall include infection control practices **[**for**]** **related to blood and body fluid precautions (that is, personal protective equipment), isolation practices, tuberculosis education, and use of protective vaccines. Additional orientation shall be directed to** the employee's specific area of service **[**and the rationale for the practices**]**.

8:43G-[14.8] 14.7 Infection control continuous quality improvement methods

The infection control **[**practitioner**]** **professional** shall develop and implement a program of continuous quality improvement that is integrated into the hospital continuous quality improvement program and includes regularly collecting and analyzing data to help determine the effectiveness of infection control practices. When corrective actions need to be taken based on data collected, the infection control committee shall recommend,

implement, and monitor those actions. The infection control **[**committee**]** **program** shall supervise these continuous quality improvement activities. **These quality improvement activities shall be overseen by the continuous quality improvement program (See N.J.A.C. 8:43G-27, Continuous Quality Improvement).**

SUBCHAPTER 20. EMPLOYEE HEALTH

8:43G-20.2 Employee health services

(a) - (c) (No change.)

[(d) Each new employee, including members of the medical staff employed by the hospital, upon employment, shall receive a two-step Mantoux tuberculin skin test with five tuberculin units of purified protein derivative. The only exceptions are employees with documented negative Mantoux skin test results (zero to nine millimeters of induration) within the last year (which will count as the first step; a second step shall be given prior to employment), employees with documented positive Mantoux skin test results (10 or more millimeters of induration), employees who received appropriate medical treatment for tuberculosis, or when medically contraindicated. Results of the Mantoux tuberculin skin tests administered to new employees shall be acted upon as follows:

1. If the first step of the Mantoux tuberculin skin test result is less than 10 millimeters of induration, the test shall be repeated one to three weeks later.

2. If the Mantoux test is 10 millimeters or more of induration, a chest x-ray is performed and, if necessary, followed by chemoprophylaxis or therapy.

3. Any employee with positive results shall be referred to a physician and shall be excluded from work until authorized in writing to return to work by the employee health physician.]

(d) Tuberculosis screening: The facility shall establish policies and procedures for the detection and control of the transmission of *M. tuberculosis* that include, but are not limited to, developing a Tuberculosis Exposure Control Plan ("TB plan"), according to the guidelines set forth in Centers for Disease Control (CDC) "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994," The Morbidity and Mortality Weekly Report published by the Epidemiology Program Office, Centers for Disease Control and Prevention (CDC) and available from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402-9325, (MMWR), October 28, 1994, Volume 43, Number RR-13, p. i-132, pursuant to the Occupational Safety and Health Act (OSH Act) of 1970, incorporated herein by reference, as amended and supplemented.

1. Newly hired employees: The facility shall establish policies and procedures that will identify a new employee's baseline status of exposure to *M.*

***tuberculosis*. Upon employment, the facility shall administer a two-step Mantoux tuberculin skin test, using five tuberculin units of purified protein derivative, to all employees. Employees are defined for the purposes of this subsection, as full and part-time employees, volunteer staff, and physicians, either salaried by the facility or with clinical privileges to provide medical care at the facility.**

i. Employees with a "negative" (less than 10 mm of induration or less than five mm of induration if the individual is immunosupressed) result following the first Mantoux skin test are administered a second test in one to three weeks.

ii. Employees with a "positive" (greater than 10 mm of induration or greater than five mm of induration if the individual is immunosupressed) result following either the first or second test are referred for a medical evaluation to determine whether there is evidence of latent tuberculosis infection or active tuberculosis disease.

(1) The medical evaluation shall include, but is not limited to, a chest X-ray.

(2) The facility shall permit employees with positive Mantoux test results to begin working after the employee has submitted written medical clearance to the facility.

iii. Exceptions:

(1) Employees who provide documentation of negative results of a single Mantoux skin test performed within the 12 months preceding the start of employment shall receive only one Mantoux skin test upon hire.

(2) Employees with prior documentation of negative results of two Mantoux skin tests performed within 12 months preceding the start of employment, and without signs and symptoms of active tuberculosis, shall not be required to be tested upon hire; however, a Mantoux skin test shall be required within 12 months of the last tuberculin skin test.

(3) Employees who provide documentation of positive Mantoux skin test results shall be exempt from screening.

(4) Employees who provide documentation of having received and completed appropriate medical treatment for active tuberculosis disease or latent tuberculosis infection shall be exempt from screening.

2. Periodic screening of personnel: The facility shall establish policies and procedures for the periodic screening of *M. tuberculosis* in eligible personnel, including, but not limited to:

i. Testing: The facility shall administer a Mantoux skin test to all tuberculin-negative employees annually at minimum. Frequency of testing shall be determined by the level of risk assigned by the facility's TB plan.

ii. Recordkeeping: The facility shall submit the results of employee Mantoux tuberculin testing bi-annually to the New Jersey Department of Health and Senior Services, on forms provided by the Department, at the address listed below.

3. Further information: Questions regarding tuberculosis control may be directed to:

New Jersey Department of Health and Senior Services
Tuberculosis Program
PO Box 369
Trenton, NJ 08625-0369
(609) 588-7522

[(e) Each employee, including members of the medical staff employed by the hospital, shall receive an annual Mantoux tuberculin skin test. The only exceptions are those employees exempted at (d) above. Results of positive Mantoux tuberculin skin tests administered to employees shall be acted upon in accordance with (d)2 above.**]**

[(f)]**(e) Rubella screening:** Each employee, including members of the medical staff employed by the hospital, shall be given a rubella screening test using the rubella hemagglutination inhibition test or other rubella screening test **[**within six months of the effective date of this subchapter**]**. The only exceptions are employees who can document seropositivity from a previous rubella screening test or who can document innoculation with rubella vaccine, or when medically contraindicated.

[(g)] **1.** (No change in text)

[(h)] **(f) Measles (Rubeola) Screening:** Each employee, including members of the medical staff employed by the hospital, born in 1957 or later shall be given a measles (rubeola) screening test using the Hemagglutination inhibition test or other rubeola screening test. The only exceptions are employees who can document receipt of live measles vaccine on or after their first birthday, physician-diagnosed measles, or serologic evidence of immunity.

[(i)] **1.** (No change in text)

Recodify existing (j) – (k) as (g)-(h) (No change in text)

[(l)] **(i)**The hospital shall comply with the reporting requirements of the Department of Health **and Senior Services'** Division of Epidemiology, Environmental and Occupational Health Services for tuberculin and rubella test results, pursuant to N.J.A.C. 8:57. Information regarding testing and reporting can be obtained from:

New Jersey State Department of Health **and Senior Services**
Communicable Disease Control Services
P.O. Box 369
Trenton, NJ 08625-0369

Recodify existing (m) – (o) as (j)-(l) (No change in text)

SUBCHAPTER 24. PLANT MAINTENANCE AND FIRE AND EMERGENCY PREPAREDNESS

8:43G-24.8 Physical plant general compliance for new construction, alteration or renovation

(a) The hospital shall comply with the New Jersey Uniform Construction Code (N.J.A.C. 5:23 under Use Group I-2), standards imposed by the United States Department of Health and Human Services (HHS), the New Jersey Departments of Health **and Senior Services** and Community Affairs, and the Guidelines for **Design and** Construction **[**and Equipment**]** of Hospital and **Health Care [**Medical**]** Facilities (**[**1987**]** **2001** edition, as published by The American Institute of Architects Press, 1735 New York Ave., NW, Washington, D.C. 20006, Pub. No. **[**ISB N0-913962-96-1**]** **ISBN 1-57165-002-4,**) **as amended and supplemented, incorporated herein by reference**. In order to avoid conflict between N.J.A.C. 5:23 and the other standards listed above, Sections 501.3, 610.4.1, 704.0, 705.0, 706.0, 708.0, and 916.5 of the 1987 BOCA Basic Building Code of the New Jersey Uniform Construction Code shall not govern with respect to health care facilities.

(b) The hospital shall submit plans and specifications to **[** the Construction and Monitoring Program, Health Facilities Evaluation, New Jersey Department of Health, CN 367, Trenton, N.J. 08625-0367**]** **Health Plan Review, Division of Codes and Standards, Department of Community Affairs, P.O. Box 815, Trenton, New Jersey 08625-0815**, for approval prior to construction, alteration, or renovation.

8:43G-24.9 [(Reserved)] Construction and renovation

(a) Whenever construction and renovation projects are planned in and around a health care facility, a risk assessment shall be conducted to determine the impact of the project on patient areas, personnel, and mechanical systems.

1. The infection control program shall review areas of potential risk and populations at risk. The infection control program shall approve control measures, if necessary.

(b). The design phase shall include commissioning specifications of ventilation requirements used during and at completion of the construction project.

(c). An education program shall be established for facility employees of the areas affected, the contractor's employees, and the contractor to define the impact, risks, interventions and compliance issues.